

### **REMARKS**

Prior to the present amendment, claims 26-33 were pending. Claims 1-20 were canceled by a preliminary amendment filed July 19, 2005. By the present amendment, applicants have canceled claim 32 and amended claims 26 and 33. No new matter has been added. Accordingly, claims 26-31, and 33 are under examination.

### **Rejection under 35 U.S.C. § 103 over Eschenfelder and Baldwin**

On page 2 of the office action, the examiner rejects claims 26-25, 32, and 33 under 35 U.S.C. § 103(a) over Eschenfelder (*US 4,944,943*) and Baldwin (*US 5,098,707*). The examiner asserts that Baldwin teaches treatment of vascular disease that includes use of compositions comprising streptokinase and a carrier that is pharmacologically acceptable for rectal administration. The examiner acknowledges that Baldwin does not disclose use of the composition for treating hemorrhoid disease. According to the examiner, Eschenfelder teaches a method of treating vascular diseases such as hemorrhoid disease using a composition comprising streptokinase.

The examiner states that one skilled in the art would have been motivated to combine the teachings of the cited references because “the addition of an antithrombotic agent to the composition makes the composition suitable for a wider variety of purposes,” as allegedly taught by Eschenfelder. The examiner further states that one skilled in the art would have had a reasonable expectation of success in combining the teachings because both cited references

“teach the manufacture of a composition comprising streptokinase that is suitable with multiple carriers.” Thus, the examiner concludes that the invention is obvious.

Applicants respectfully disagree. Merely in order to expedite prosecution, applicants have canceled claim 32 and amended claim 26. The claimed method for treating hemorrhoid disease as amended now includes administering a pharmaceutical composition “consisting essentially of” a thrombolytic protein, wherein the pharmaceutical composition is administered rectally.

Baldwin fails to disclose administering a pharmaceutical composition “consisting essentially of” a thrombolytic protein for treatment of hemorrhoid disease. As acknowledged by the examiner, Baldwin is devoid of any disclosure or suggestion of a method for treating hemorrhoid disease. In addition, the “compositions to be employed in the practice of the [Baldwin] invention whether parenteral, oral or suppository compositions comprises an imidazole compound in a pharmaceutically acceptable carrier.” See col. 23, lines 65-69 of Baldwin. Accordingly, the compositions disclosed in Baldwin require imidazole. See also col. 24, lines 13-19 of Baldwin, as cited by the examiner.

Eschenfelder fails to rectify the deficiencies of Baldwin. Eschenfelder does not disclose administering a pharmaceutical composition “consisting essentially of” a thrombolytic protein for treatment of hemorrhoid disease. Eschenfelder discloses “a mixture of a substance having thrombolytic activity and of an anti-thrombolytic substance” (emphasis added). See col. 1, lines

23-25 of Eschenfelder. The passages of Eschenfelder that were cited by the examiner also require the mixture.

Accordingly, one skilled in the art would have lacked any motivation to combine the teachings and would have had no reasonable expectation of success in arriving at the claimed method for treating hemorrhoid disease, which includes rectally administering a pharmaceutical composition “consisting essentially of” a thrombolytic protein. The cited references, individually and in combination, fail to obviate the claimed invention. Applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejection under 35 U.S.C. § 103 over Eschenfelder, Baldwin, Ivy, and Oh**

On page 5 of the office action, the examiner rejects claims 26-33 under 35 U.S.C. § 103(a) over Eschenfelder and Baldwin as applied to claims 26-28, 32, and 33 above, and in further view of Ivy (*US 5,720,962*) and Oh (*WO 01/22935*).

Applicants believe that the claim amendments and arguments outlined above, overcome the present rejection. For example, none of the cited references, individually or in combination, disclose or suggest a method for treating hemorrhoid disease, which includes rectally administering a pharmaceutical composition “consisting essentially of” a thrombolytic protein.

**Conclusion**

In view of the foregoing amendments and remarks, entry of the amendments and favorable consideration of the claims are respectfully requested. If the examiner has any questions or concerns regarding this amendment, she is invited to contact the undersigned at the telephone number listed below. If any fees are due or any over overpayment made in connection with this paper, please charge or credit our Deposit Account No.: 08-2461.

Respectfully submitted,

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